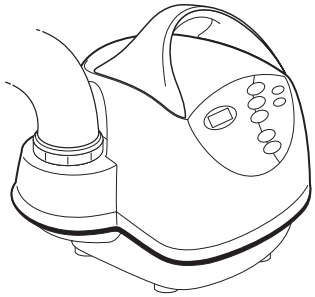
775

Bair Hugger*

Temperature Management Unit
Model 775



Operator's Manual

Bair Hugger*
Temperaturmanagementgerät
Modell 775 Benutzerhandbuch

Bair Hugger* Unité de contrôle de température, modèle 775
Manuel de l'utilisateur

Bair Hugger* Unità per la gestione della temperatura mMdello 775
Manuale d'uso

Bair Hugger* Unidad de control de temperatura, Modelo 775
Manual del operador

Bair Hugger* Unidade de Gestão de Temperatura Modelo 775
Manual do Utilizador

Bair Hugger* Model 775
temperatuurregelunit
Gebruikershandleiding

Bair Hugger*
Temperaturstyringsenhed
Model 775 Brugervejledning

Bair Hugger*
Temperaturregleringsenhet,
Modell 775 Bruksanvisning

Bair Hugger*
Temeraturadministrasjonsenhet
Modell 775 Brukerhåndbok

Bair Hugger* Lämpötilan valvontayksikkö edestä
Malli 775 Käyttöopas

Bair Hugger* Μονάδα Διαχείρισης Θερμοκρασίας Μοντέλο 775 Εγχειρίδιο Χρήσης

ベアーハガー* 体温管理装置モデル775 取扱説明書

Bair Hugger* Dmuchawa
Model 775 Instrukcja obsługi

Bair Hugger* Hőmérséklet szabályozó egység 775-ös
Modell Használati utasítás

Bair Hugger* Termoregulační jednotka, Model 775
Návod k obsluze

Bair Hugger* Temperatūros kontrolės įrenginys, Modelis 775
Naudotojo vadovas

Bair Hugger* Устройство управления температурой, модель 775 Руководство по эксплуатации

Bair Hugger* 775 型温度管理仪
操作员手册

Total Temperature Management System

775

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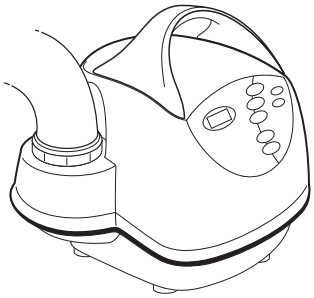
Temperature Management Unit
Model 775



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Introduction

Description of the Total Temperature Management System

The Bair Hugger* brand Total Temperature Management system consists of a Model 775 forced-air temperature management unit (with optional rolling stand, and other accessories) and disposable components, including Bair Hugger forced-air blankets, Bair Paws* patient warming gowns and the 241* blood/fluid warming set. You can use the Model 775 temperature management unit in all clinical settings where the patient may become too warm or too cold; including the operating room to provide patient temperature management.

This manual includes operating instructions and unit specifications for the Model 775 temperature management unit. For information about using Bair Hugger blankets, Bair Paws gowns, or the 241 blood/fluid warming set with the Model 775 temperature management unit, refer to the "Instructions for Use" included with each of these disposable components.

Indications

The Bair Hugger Total Temperature Management system is intended to prevent and treat hypothermia. In addition, the temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The temperature management system can be used with adult and pediatric patients.

Contraindications

Do not apply heat to lower extremities during aortic cross-clamping. Thermal injury may occur if heat is applied to ischemic limbs.

Warnings

1. Do not leave patients with poor perfusion unmonitored during prolonged warming therapy sessions. Thermal injury may result.
2. The Bair Hugger temperature management unit has been designed to operate safely ONLY with Arizant Healthcare* disposable components. Use with other products may cause thermal injury. (To the full extent permitted by law, the manufacturer and/or importer declines all responsibility for thermal injury resulting from the unit being used in conjunction with non-Arizant Healthcare products.)
3. Do not warm patients with the temperature management unit hose alone. Thermal injury may result. Always connect the hose to a Bair Hugger blanket or Bair Paws gown before providing therapy.
4. Do not place the non-perforated side of the blanket on the patient. Thermal injury may result. Always place the perforated side (that is, with small holes) towards the patient.

5. Do not continue temperature management therapy if the over-temp indicator light illuminates and the alarm sounds. Thermal injury may result. Unplug the unit, and contact a qualified service technician.
6. Do not continue 241 blood/fluid warming therapy if the over-temp indicator light illuminates and the alarm sounds. Immediately stop fluid flow, and discard the blood/fluid warming set. Unplug the temperature management unit, and contact a qualified service technician.
7. Do not use a forced-air warming device over transdermal medication. Increased drug delivery and patient injury or death may occur.
8. Do not allow the patient to lie on the warming unit hose or allow the hose to directly contact the patient's skin during patient warming; thermal injury may result.
9. Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
10. Reusable blankets made from woven fabric, or blankets without discrete, visible holes, can cause the safety system of this unit to fail, which may result in serious thermal injury. This warming unit has been designed to operate safety ONLY with Bair Hugger blankets and Bair Paws gowns.

Cautions

1. Except for specific blanket models, Bair Hugger blankets are not sterile and are all intended for single patient use ONLY. Placing a sheet between the Bair Hugger blanket and the patient does not prevent contamination of this product.
2. Monitor the temperature and cutaneous response of patients who are incapable of reacting, communicating and/or who are without a sense of feeling every 10-20 minutes or according to institutional protocol. Monitor the patient's vital signs regularly. Adjust air temperature or discontinue therapy when the therapeutic goal is reached or if vital sign instability occurs. Notify physician of vital sign instability immediately.
3. Do not leave pediatric patients unattended during therapy.
4. Do not initiate temperature management therapy unless the temperature management unit is safely placed on a hard surface or securely mounted. Otherwise, injury may result.
5. To prevent tipping, clamp the Model 775 temperature management unit to an IV pole at a height that provides stability. We recommend clamping the unit no higher than 44" (112 cm) on an IV pole with a minimum 28" (71 cm) diameter wheelbase. Failure to do so may result in IV pole tipping, catheter site trauma, and patient injury.

6. Electrical shock hazard. Do not disassemble the temperature management unit unless you are a qualified service technician. There are electrically live parts with in the unit when it is connected to a power source, even when the unit is in *Standby* mode.

Notices

1. The Bair Hugger temperature management unit meets medical electronic interference requirements. If radio frequency interference with other equipment should occur, connect the unit to a different power source.
2. Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare professional.
3. To reliably ground this Bair Hugger warming unit, only connect to receptacles marked "Hospital Only" or "Hospital Grade".

Proper Use and Maintenance

Arizant Healthcare assumes no responsibility for the reliability, performance, or safety of the temperature management unit if the following events occur:

- Modifications or repairs are performed by unqualified personnel.
- The unit is used in a manner other than that described in the Operator's or Service Manual.
- The unit is installed in an environment that does not meet the appropriate electrical and grounding requirements.

Read Before Servicing Equipment

All repair, calibration, and servicing of the temperature management unit require the skill of a qualified, medical equipment service technician who is familiar with good practice for medical device repair. If service does not require the manufacturer's attention, the Model 775 Service Manual provides the technical information needed to service the unit. Perform all repairs and maintenance in accordance with the instructions in the Service Manual. For additional service information please contact Arizant Healthcare Inc.

Overview and Operation

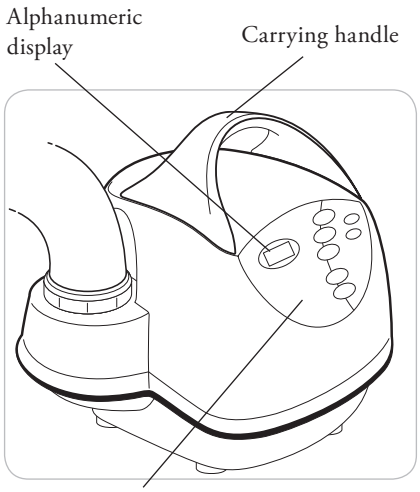

Figure A. Model 775 temperature management unit – front view

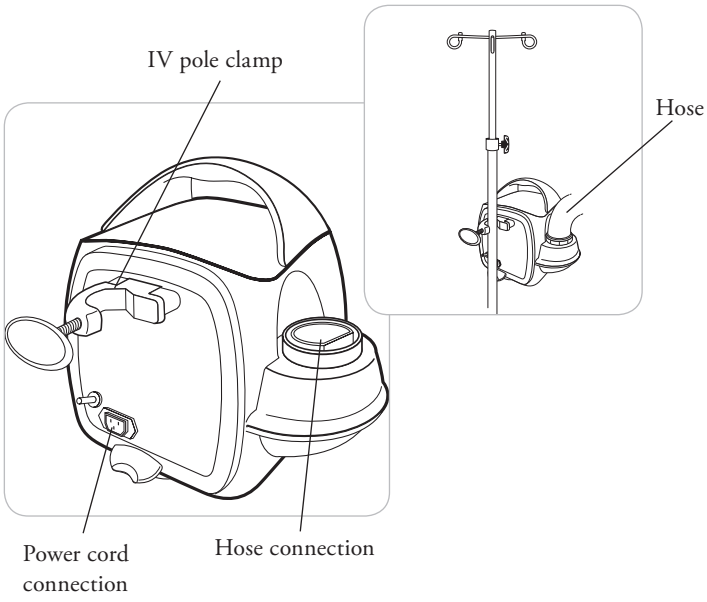

Figure B. Model 775 temperature management unit – rear view

Unit Power-On-Reset

The Model 775 temperature management unit automatically performs the following power-on-reset sequence after you connect the unit to a properly grounded power source:

- Performs all self-test functions.
- Illuminates indicator lights and all pixels in the alphanumeric display momentarily.
- Displays the text "MD 700's" and the software revision level in the alphanumeric display.
- Sounds the alarm (three low-level clicks).
- Enters the *Standby* mode with the high fan setting selected by default.

Note: The low fan setting indicator light will not illuminate during power up.

If the temperature management unit looses power for less than 1 second, the unit's software will return the unit to the operating mode you selected prior to the power loss. However, if the temperature management unit loses power for longer than 1 second, the unit's software will reset when you restore power. The unit will then enter the *Standby* mode.

Overview of Control Panel

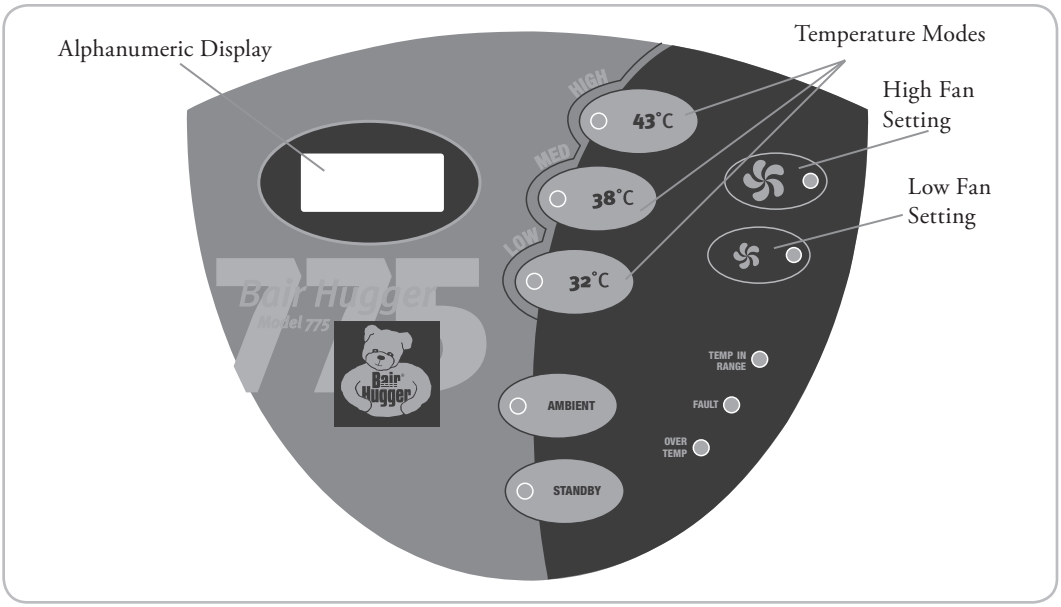

Figure C. Model 775 temperature management unit control panel

ALPHANUMERIC DISPLAY

The alphanumeric display shows the temperature at the Bair Hugger blanket or Bair Paws gown end of the temperature management unit hose in degrees Celsius.

TEMPERATURE MODES

- Press the **32°C** (Low), **38°C** (Med), or **43°C** (High) button to select the desired temperature.
- Press the *Ambient* button to supply room temperature air.

When you select a temperature mode, the following events occur:

- Corresponding temperature indicator and fan setting lights illuminate.
- Blower operates at selected fan speed.
- Fan setting indicator light illuminates.
- Temperature at the blanket or gown end of the hose appears in the alphanumeric display.
- Heater activates except in *Ambient* mode.
- Temperature mode timer activates (or resets itself if changing from one temperature mode to another).

AIRFLOW MODES

The Model 775 has two preset fan speed settings: a default or high fan setting ( )and a reduced or low fan setting ( ). The Model 775 will reset/default to the high fan setting each time the unit is powered up or *Standby* is selected. The low fan setting ( ) may be pre-selected while in *Standby* prior to selecting the desired temperature.

STANDBY

Upon power up, the warming unit defaults to *Standby* and the high fan setting. When the unit is in **32°C** (Low), **38°C** (Med), or **43°C** (High) or *Ambient* mode, press the *Standby* button to place the unit in *Standby* mode.

When you select the *Standby* mode, the following events occur:

- *Standby* indicator light illuminates.
- Blower and heater are turned OFF.
- Alphanumeric display deactivates.
- Alarm and fault detection functions remain active.
- Operating timer pauses.
- Airflow mode resets/defaults to the high fan setting.

TEMP IN RANGE INDICATOR LIGHT

The *Temp in Range* indicator light illuminates when the temperature at the blanket or gown end of the hose is ±1.5°C of the selected setting; this indicator light does not illuminate in the *Ambient* mode.

FAULT INDICATOR LIGHT

When a system fault occurs, the amber *Fault* indicator light flashes and an alarm sounds.

Please refer to What to Do in Case of a Fault Condition on page 9 for additional information.

OVER-TEMP INDICATOR LIGHT

If the unit senses an over-temperature condition, the red *Over-temp* indicator light flashes and an alarm sounds.

Please refer to What to Do in Case of an Over-Temperature Condition on page 9 for additional information.

Mounting the Temperature Management Unit to an IV Pole

CAUTION

To prevent tipping, clamp the Model 775 temperature management unit to an IV pole at a height that provides stability. We recommend clamping the unit no higher than 44" (112 cm) from the floor on an IV pole with a minimum 28" (71 cm) diameter wheelbase. Failure to do so may result in IV pole tipping, catheter site trauma, and patient injury.

METHOD

To mount the Model 775 temperature management unit to an IV pole, simply turn the clamp handle clockwise to tighten the clamp on the IV pole and counterclockwise to release it. Ensure the IV pole bumper rests against the pole. See Figure D.

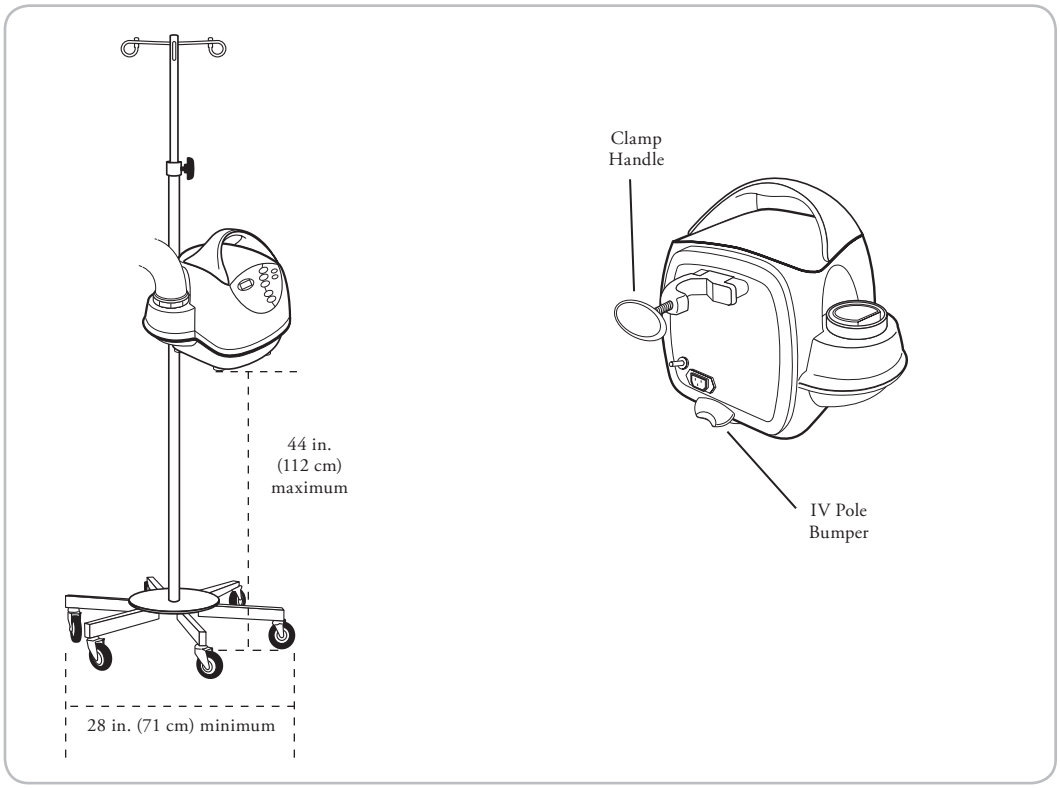

Figure D. Model 775 on an IV Pole

Instructions for Use

The instructions below describe how to operate the Model 775 temperature management unit. For information about using Bair Hugger blankets, Bair Paws gowns, or the 241 blood/fluid warming set with the Model 775 unit, refer to the Instructions for Use included with each of these disposable components.

1. If the Model 775 temperature management unit is not mounted on an IV pole or Bair Hugger rolling stand, place the unit on a flat, hard, dry surface, such as a table, before beginning temperature management therapy. Do not place the unit on a soft, uneven or visibly wet surface such as a bed, or the air intake may become blocked and cause the unit to overheat.

2. Insert the end of the temperature management unit hose into the hose port of a Bair Hugger blanket or Bair Paws gown. Use a twisting motion to ensure a snug fit. A visual marker (Figure E) is located around the mid section of the hose end to guide the depth of hose insertion.

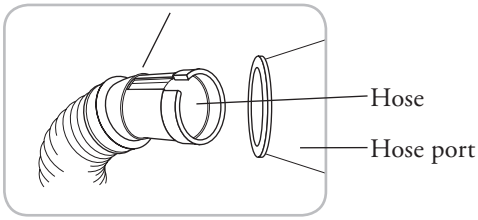

Figure E.

3. Connect the temperature management unit to a properly grounded power source. The unit will be in *Standby* mode and the *Standby* indicator light will illuminate. The high fan setting ( ) will be pre-selected by default with its indicator light illuminated. The low fan setting ( ) may be pre-selected prior to selecting the desired temperature mode.

4. Press the appropriate button (i.e., **32°C**, **38°C**, **43°C**, or *Ambient*) to select the desired temperature. This will turn the blower and heater ON. When the unit reaches the selected temperature, the *Temp in Range* indicator light will illuminate; this indicator light does not illuminate in the *Ambient* mode.

5. Monitor the temperature and cutaneous response of patients who are incapable of reacting, communicating and/or who are without a sense of feeling every 10-20 minutes or according to institutional protocol. Monitor the patient's vital signs regularly. Adjust air temperature or discontinue therapy when the therapeutic goal is reached or if vital sign instability occurs. Notify physician of vital sign instability immediately.

6. Press the *Standby* button when temperature management therapy is complete and discard disposable components.

7. Unplug the temperature management unit to disconnect it from the power source.

Note: At any time, the fan speed setting can be switched between high fan setting ( ) and low fan setting ( ) by pressing the corresponding button. However, these buttons will not place the unit into *Standby*.

Viewing the Temperature Mode Timer

The temperature mode timer records the amount of time the temperature management unit has been operating in the selected temperature mode. The timer resets itself every time you select a different temperature mode.

To view the temperature mode timer, press the button and hold for 2 seconds for the current temperature mode. The alphanumeric display will show the temperature mode time, then go back to showing the temperature mode setting.

What to Do in Case of an Over-Temperature Condition

If an over-temperature condition occurs, the red *Over-temp* indicator light flashes and an alarm sounds. The unit automatically turns the heater, blower, and operating mode indicator lights OFF. The control panel will not respond to commands.
Note: Pressing any button will silence the alarm.

IF AN OVER-TEMPERATURE CONDITION OCCURS:

1. Discontinue all temperature management therapy. If you are using the 241 blood/fluid warming system, immediately stop fluid flow and discard the blood/fluid warming set.
2. Unplug the temperature management unit.
3. Contact a qualified service technician.

What to Do in Case of a Fault Condition

The Model 775 temperature management unit's software recognizes several non-hazardous conditions and reports those conditions as faults. When a system fault occurs, the software stores the fault code in memory, the amber *Fault* indicator light flashes, and an alarm sounds. The control panel will not respond to commands.
Note: Pressing any button will silence the alarm.

IF A FAULT CONDITION OCCURS:

1. Unplug the temperature management unit and wait for 5 minutes.
2. Reconnect the temperature management unit to a grounded power source. The unit will perform the normal power-on-reset sequence and then enter the *Standby* mode.
3. Reselect the temperature setting.
4. If the unit does not return to normal operation, contact a qualified service technician.

General Maintenance

Cleaning the Cabinet and Hose

WARNING

Do not immerse the cabinet or hose while cleaning. Moisture will damage the components, and thermal injury may result.

PRECAUTIONS

- Do not use a dripping wet cloth to clean the cabinet. Moisture may seep into the electrical contacts and damage the components.
- Do not use alcohol or other solvents to clean the cabinet. Solvents may damage the labels and other plastic parts.

METHOD

1. Disconnect the temperature management unit from the power source before cleaning.
2. Wipe the cabinet and the outside of the hose with a damp, soft cloth and a mild detergent or antimicrobial spray.
3. Dry with a separate soft cloth.

Technical Service and Order Placement

Technical Service

USA
TEL: +1-952-947-1200
+1-800-733-7775
FAX: +1-952-947-1400

GERMANY
TEL: +49-4154-9934-0
FAX: +49-4154-9934-20

UNITED KINGDOM
TEL: +44-1924-200-550
FAX: +44-1924-200-518

FRANCE
TEL: +33-4-42-98-14-00
Indigo (in France only): 0-820-33-90-40
FAX: +33-4-42-98-14-01

Order Placement

USA
TEL: +1-952-947-1200
+1-800-733-7775
FAX: +1-952-947-1400
+1-800-775-0002

When You Call for Technical Support

We will need to know the serial number of your Bair Hugger temperature management unit when you call us. The serial number label is located on the back of the Bair Hugger temperature management unit.

In-Warranty Repair and Exchange

USA

Call Arizant Healthcare customer service if your Model 775 temperature management unit requires factory service. A customer service representative will give you a Return Authorization (RA) number. Please use this RA number on all correspondence concerning your temperature management unit. Your customer service representative will also send a shipping carton to you at no charge, if needed. Call your local supplier or sales representative to inquire about borrowing a temperature management unit while we service your unit. For more detailed instructions on returning units for service, please refer to the Model 775 service manual.

OUTSIDE OF THE USA

Contact your local distributor concerning in-warranty repair and exchange.

Specifications

Physical Characteristics

DIMENSIONS	13″ high x 13″ deep x 14″ wide 33 cm high x 33 cm deep x 36 cm wide
WEIGHT	16 lb (7.3kg)
RELATIVE NOISE LEVEL	53 dBA (High fan setting) 48 dBA (Low fan setting)
HOSE	Flexible, compatible with the Bair Hugger brand 241 blood/fluid warming system.
FILTRATION SYSTEM	0.2 µm air filter
RECOMMENDED FILTER CHANGE	Every 6 months or 500 hours of use.
MOUNTING	Can be clamped to an IV pole, placed on a hard surface, or mounted to the rolling stand accessory.

Temperature Characteristics

RECOMMENDED OPERATING ENVIRONMENT	15°C-25°C
TEMPERATURE CONTROL	Electronically controlled.
HEAT GENERATED	High fan setting: 1600 BTU/hr (average), 470 W (average) Low fan setting: 1330 BTU/hr (average), 390 W (average)
OPERATING TEMPERATURES	Average temperatures at the end of the hose: HIGH: 43° ± 1.5°C 109.4° ± 2.7°F MED: 38° ± 1.5°C 100.4° ± 2.7°F LOW: 32° ± 1.5°C 89.6° ± 2.7°F

Safety System

THERMOSTAT	Independent electronic circuit; thermal cutoff shuts the heater OFF to ensure hose end air remains below 56°C (53°C ± 3°C typical); back-up over-temperature detection at hose inlet.
ALARM SYSTEM	Over-temperature (≤56°C, 53°C ± 3°C typical): red Over-temp indicator light flashes, alarm sounds, heater and blower shut down, operating indicator lights turn OFF, control panel becomes unresponsive. Fault: amber Fault indicator light flashes, alarm sounds.
OVERCURRENT PROTECTION	Dual input fused lines.

Electrical Characteristics

HEATING ELEMENT	1400 W Resistive
LEAKAGE CURRENT	Meets UL 60601-1 and IEC 60601-1 requirements.
BLOWER MOTOR	Operating speed: 4,700 rpm (high fan setting), 4,100 rpm (low fan setting) Airflow: up to 48 cfm or 23 L/s
POWER CONSUMPTION	Peak: 1550 W Average: 800 W
POWER CORD	15 ft., SJT, 3 cond., 13 A 15 ft., SJT, 3 cond., 15 A 4.6 m, HAR, 3 cond., 10 A
DEVICE RATINGS	110-120 VAC, 50/60 Hz, 11.7 A, or 220-240 VAC, 50/60 Hz, 7.2 A, or 100 VAC, 50/60 Hz, 15 A
FUSES	12 A (110 - 120 VAC) 8 A (220 - 240 VAC) 15 A (100 VAC)
CERTIFICATIONS	IEC 60601-1; EN 60601-1-2; UL 60601-1;CAN/CSA-C22.2, No. 601.1, EN 55011; ASTM F2196-02
CLASSIFICATION	Classified under IEC 60601-1 Guidelines (and other national versions of the Guidelines) as Class I, Type BF, Ordinary equipment, Continuous operation. Not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide. Classified by Underwriters Laboratories Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1, ASTM F2196-02, and Canadian/CSA C22.2, No. 601.1. Classified under the Medical Device Directive as a Class IIb device.
DIAGNOSTICS	A qualified service technician can perform over-temperature detection system testing, temperature output testing, operating temperature calibration, and fault code troubleshooting.

Definition of Symbols

The following symbols may appear on the product's labeling or exterior packaging.

Equipotentiality plug (ground)

Fuse

Attention, consult appropriate documents

Nonexplosion proof

Dangerous voltage

Type BF equipment (patient applied)

Voltage, alternating current (AC)

Special refuse, discard separately

Protective earth ground

No free hosing

High fan setting

Low fan setting